REMARKS

The specification has been amended to insert language that MET could be used as the hormone for culturing seedlings. Support for this amendment can be found in the claims as originally filed.

New claims 40-42 have been added. New claim 40 is directed to a method for producing a transgenic cotton plant and is similar to claim 31 with additional steps as described in the process set forth in Example 3. Support for this new claim can be found in Example 3 and in the general description of the invention as found at pages 6-7 of the application. New claim 41 is similar to claim 36. New claim 42 is similar to claim 37.

It is submitted that these amendments do not constitute new matter, and their entry is requested.

Rejection under 35 U.S.C. 112 first paragraph.

Claims 4, 5, 7, 8, 10, 11, 13-26, 28, 30-32, 36, and 37-39 stand rejected under 35 U.S.C. 112, first paragraph for failure to comply with the enablement requirement. The Examiner asserts that the specification does not enable the broad scope of the claimed subject matter. Applicants traverse this rejection.

Specifically, Applicants assert that the teachings of the instant application would instruct one of ordinary skill in the art how to transform different varieties of cotton using different vectors and different marker genes. How a teaching is set forth, by specific example or broad terminology, is not important. *See*, *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). Thus, the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious.

As Applicants have previously established, the prior art clearly demonstrates that different varieties of cotton could be regenerated and transformed as of the effective filing date of the present application. Thus, although in the early days of cotton regeneration and transformation, the Coker

varieties of cotton were the ones that were able to be successfully regenerated and transformed, other varieties of cotton could be successfully regenerated and transformed at the effective filing date of the present invention. Applicants demonstrated this fact by submitting copies of several references, namely, Hansen et al., Cousins et al., Gould et al. and Yenofsky et al. (see the Amendment filed on 26 November 2006 for a full citation of these references). These references, reflecting the state of the art at the time of the present invention, clearly establish that many different cultivars of cotton can be transformed. The Examiner has not provided any sound scientific evidence or reasoning to dispute the teachings of these references. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir.1993); *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1973) ("It is incumbent upon the Patent Office, whenever a rejection on this basis [i.e. doubt of the objective truth of statements in the specification] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."). Thus, Applicants submit that the prior art, as of the effective filing date of the present invention, establishes the enablement for the breadth of the claims for cotton varieties other than Coker.

Similarly, Applicants have previously established that the prior art clearly demonstrates that different strains of *Agrobacterium tumefaciens* could be used to transform cotton as of the filing date of the present application. Thus, although in the early days of cotton transformation, *Agrobacterium tumefaciens* LBA4404 was the strain used for cotton transformation, other strains were used for cotton transformation at the effective filing date of the present invention. Applicants demonstrated this fact by submitting copies of several references, namely, Hansen et al., Cousins et al., Gould et al. and Yenofsky et al. (see the Amendment filed on 26 November 2006 for a full citation of these references). These references, reflecting the state of the art at the time of the present invention, clearly establish that different strains of *Agrobacterium tumefaciens* can be used to transform cotton. The fact that other strains of *Agrobacterium tumefaciens*, e.g., AGL1, could be used to transform cotton was further established by the Declaration Under 37 C.F.R. 1.132 by Dr. Yan Hong submitted

with the Amendment filed on 26 November 2006. The Hong Declaration is entirely consistent with the teachings of the prior art, and sets forth results achieved using the claimed invention. The fact that Dr. Hong is not a disinterested party does not detract from the results that were described in the Rule 132 Declaration which demonstrates the broad applicability of the present invention. The Examiner has not provided any sound scientific evidence or reasoning to dispute the teachings of these references or the showing by Dr. Hong that other *Agrobacterium tumefaciens* strains can be used to transform cotton. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir.1993); *In re Marzocchi*, 169 USPQ 367 (CCPA 1973). Thus, Applicants submit that the prior art, as of the effective filing date of the present invention, establishes the enablement for the breadth of the claims for strains of *Agrobacterium tumefaciens* other than LBA4404.

Applicants further submit that the prior art clearly demonstrates that different selectable marker genes or genes of interest could be used in the transformation of cotton. For example, Cousins et al. (cited above) shows the use of neomycin phosphotransferase or β-glucuronidase as markers in the transformation of cotton. Yenofsky et al. (cited above) shows the use of lectin genes in the transformation of cotton. In addition, Umbeck (US 5,159,135) shows the use of chloramphenicol acetyl transferase as a marker in the transformation of cotton, as well as the transformation of several cultivars of cotton. Barry et al. (US 6,441,277) shows the transformation of cotton with the fructose-1,6-bisphosphate aldolase gene of interest. These references, reflecting the state of the art at the time of the present invention, clearly establish that different selectable marker genes and genes of interest can be used in the transformation of cotton. The fact that other selectable marker genes, e.g., green fluorescent protein, could be used in the transformation of cotton was further established by the Declaration Under 37 C.F.R. 1.132 by Dr. Yan Hong submitted with the Amendment filed on 28 November 2006. The Hong Declaration is entirely consistent with the teachings of the prior art, and sets forth results achieved using the claimed invention. The fact that Dr. Hong is not a disinterested party does not detract from the results that were described in the Rule 132 Declaration which demonstrates the broad applicability of the present invention. The Examiner

has not provided any sound scientific evidence or reasoning to dispute the teachings of these references or the showing by Dr. Hong that other selectable marker genes or genes of interest can be used in the transformation of cotton. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir.1993); *In re Marzocchi*, 169 USPQ 367 (CCPA 1973). Thus, Applicants submit that the prior art, as of the effective filing date of the present invention, establishes the enablement for the breadth of the claims for selectable marker genes or genes of interest other than a kanamycin resistance gene.

These references, demonstrate that a skilled artisan would expect and accept Applicants' statement at page 10 of the specification:

> [I]t is believed that the present method has broad applicability to transformation of cotton varieties, as it overcomes or minimizes several of the problems associated with previous work relating to cotton transformation (such as breakthrough of non-transformed callus, poor explant growth and low transformation rate, poor somatic regeneration) through the use of fibrous root explants[.]

to be true with reasonable predictability, i.e., with a reasonable expectation of success.

The Examiner has contended during the prosecution of this application that there is a high level of unpredictability in the art, citing Hansen and Wright (*Trends in Plant Science* **4**:226-231, 1999) as showing that plant transformation is an art and not a science with respect to newly examined crop species. However, the overall tenor of this article is that plant transformation technology is a versatile platform. See the abstract. In fact, on page 226, right column, Hansen and Wright state that advances in tissue culture and transformation technology have increased transformation efficiencies and that many crops, previously classed as recalcitrant have now been transformed. This discussion in Hansen and Wright rebuts the Examiner's position about the high level of unpredictability in the art, although there may be a lower level of unpredictability, particularly with new crop species, of which cotton is not one in view of the history of cotton transformation that preceded the present invention.

The Examiner has also contended that there is no enablement for the use of MET because its use is not shown in any Example and no comparison has been made with and without the use of

MET. However, Applicants submit that the specification provides objective enablement for the use of MET or MET and NAA for culturing seedlings to obtain fibrous root explants. The originally filed claims also disclose the use of MET for culturing seedlings to obtain fibrous root explants. The Examiner has not provided any references or sound scientific reasoning to rebut this objective enablement. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir.1993); *In re Marzocchi*, 169 USPQ 367 (CCPA 1973).

Furthermore, Applicants submit that the analysis of the Wands factors clearly demonstrate that the presently claimed subject matter is fully enabled by the present application, especially in view of the knowledge in the art.

Nature of the invention: The invention, as set forth in the amended claims, is directed to the transformation of cotton.

Breadth of the claims: The claims, as noted by the Examiner, encompass any cotton variety, any Agrobacterium strain, any selectable marker, any media and any gene of interest. The claims are specific as to the hormones that are used in the process.

Presence or absence of working examples: The specification provides working examples showing that cotton is transformed in accordance with the presently claimed invention.

State of the prior art: The related art, as described above, clearly demonstrates that (a) cotton varieties other than Coker can be transformed by *Agrobacterium tumefaciens*, (b) *Agrobacterium tumefaciens* strains other than LBA4404 can be used to transform cotton, (c) selectable marker genes and genes of interest other than kanamycin resistance can be used in the transformation of cotton and (d) various media can be used in the transformation of cotton.

Relative skill of those in the art: The skill in the art is very high – that of a plant biotechnology researcher involved in plant transformation. Thus, Applicants submit that the specification, directed to a person of ordinary skill in the art, is directed to a person with a high level of skill.

Guidance provided in the specification: The specification provides guidance to the skilled artisan, i.e., a person of high skill in the art (see above), that the claimed subject matter is useful for the transformation of cotton varieties by *Agrobacterium tumefaciens* using selectable marker genes and genes of interest.

Predictability of the art: Applicants submit that the art is reasonably predictable with the respect to the transformation of cotton which, as the art demonstrates, was well known at the time of the present invention, including the ability to transform various cotton varieties using various *Agrobacterium tumefaciens* strains, various selectable markers and genes of interest and various media. This predictability is demonstrated by the prior art references discussed above. Applicants submit that is, a skilled artisan, a person of high skill in the present art (see above), has a reasonable expectation that cotton can be transformed as disclosed in the present application. A reasonable expectation is all that is required.

Amount of experimentation necessary: As discussed above, the present specification provides guidance concerning the transformation of cotton using fibrous root explants. This guidance is coupled with experimental data (in the application and in the Hong Declaration) which clearly demonstrates to a person of ordinary skill in the art that the claimed method can be used to transform cotton. Although some experimentation may be required in order to fully practice the invention for other cotton varieties, Applicants submit that such experimentation does not reach to the level of undue experimentation, especially in view of the teachings of the prior art. Thus, Applicants submit that any experimentation that may be required is not undue.

Applicants submit that a proper analysis of the Wands factors for the subject matter of the present invention establishes that undue experimentation is not required to practice the invention of the presently claimed scope.

In view of the above amendments and remarks, Applicants submit that the specification fully enables the full scope of the claimed subject matter. Withdrawal of this rejection is requested.

In view of the above amendments and remarks, Applicants believe that the present claims satisfy the provisions of the patent statutes and are patentable over the cited prior art. Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned to expedite the prosecution of the application.

Respectfully submitted,

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